PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/GB2004/003481	International filing date *(day/month/year)* 13.08.2004
Priority date *(day/month/year)* 14.08.2003	
International Patent Classification (IPC) or both national classification and IPC A61M16/04	
Applicant NASIR, Muhammed Aslam	

1. This opinion contains indications relating to the following items:

   - ☒ Box No. I Basis of the opinion
   - ☒ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☒ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☒ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

   If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

   If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

   For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Kroeders, M Telephone No. +31 70 340-1967

W...TTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2004/003481

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 25,33

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 25, 33

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☒ paid additional fees under protest.

   ☐ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-24, 26-32
	No:	Claims	-
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-24, 26-32
Industrial applicability (IA)	Yes:	Claims	1-24, 26-32
	No:	Claims	-

2. Citations and explanations

   see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   see form 210

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.
PCT/GB2004/003481

Re Item III.

Claims 25 and 33 were not searched in view of a lack of technical features (Article 17(2)(a)(ii) PCT). Consequently, no opinion will be formulated on the subject-matter of these claims (Article 34(4)(a)(ii) PCT).

Re Item IV.

The separate inventions/groups of inventions are:

Group 1: claims 1-24, 25
an airway device, comprising:
A) an airway tube
B) a non-inflatable cuff at the distal end of A)
and
C) hardness of the cuff material

Group 2: claims 26-32, 33
a method of manufacturing an airway device, comprising:
A) an airway tube
B) a non-inflatable cuff at the distal end of A)
by
D) steps of moulding a liquid plastic material

These groups are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

In order that an International Application may contain more than one invention, the inventions defined in the application must form "a group", namely they should be so linked, as to form a single general inventive concept (see Rule 13.1 PCT). This inventive concept finds expression in the independent claims according to the different inventions in terms of the same or corresponding special technical features. The definition "special technical features" refers to the features which, in the independent claims, involve an inventive step over the prior art.

In the present case the common or corresponding features of independent apparatus

claim 1 and independent method claims 26, 28, 30 and 31 are airway tube A) and non-inflatable cuff B), which are disclosed in combination in the documents cited in the search report and are therefore not only not involving an inventive concept over the prior art, but are not even new. The remaining features of the independent claims, namely the hardness of the cuff material C) and the steps of moulding a plastic material D) (not necessarily identical to the material specified in claim 1) are different and have different purposes.

Therefore the application is considered to encompass 2 different, separate inventions, contrary to the requirements of Rule 13.1 PCT.

Re Item V.

1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not inventive in the sense of Article 33(3) PCT. Document EP-A-0389272 discloses (the references in parenthesis applying to this document):

> an airway device comprising an airway tube (10) having a distal end and a proximal end, the distal end of which is surrounded by a laryngeal cuff (14), wherein the cuff is non-inflatable (see column 8, lines 14-16) and is pre-formed in a shape such that a face region of the cuff (14) is adapted to fit snugly over the laryngeal inlet of a patient (generic feature of an airway device), and wherein the external profile of the tube (10) is substantially uniform between the distal end of the tube where it starts to meet the cuff and the proximal end of the tube (generic feature of an airway device)

The subject-matter of claim 1 differs from this disclosure in that the face region of the cuff is formed from a material with a Shore hardness on the A scale of between 0 and 30.

The problem to be solved by the present invention may therefore be regarded as preventing damage to the laryngeal tissues of the patient.

The feature proposed in claim 1 of the present application cannot be considered

as involving an inventive step (Article 33(3) PCT) for the following reasons.

Document WO-A-00/09189 discloses values for the hardness of an inflatable cuff (see also the cited passages of documents US-A-2002/010417 and US-A-3734100). The skilled person is well aware of these values and would therefore certainly use these values as an indication for the material choice of a non-inflatable cuff.

2 Independent claims 26, 28, 30 and 31 do not meet the requirements of Article 33(1) PCT, because their subject-matter does not appear to be inventive.

All these independent claims contain one method step which is "optional". For the purpose of examination, the term "optionally" does not limit the scope of the claim. In order for the claim to be patentable, the subject-matter of the claims must be clear as to whether a certain method step is included or not.

The result for the current set of method claims is that the step relating to a second plastics material is completely disregarded. As a consequense, claim 26 becomes a standard manufacturing method (see also EP-A-1125595).
The additional features disclosed in dependent and independent claims 27 to 32 relate to further standard manufacturing methods (extruded tube, assembly of tube and cuff).

The subject-matter of the methods of manufacturing when explicitly including the step of introducing a second plastics material does not appear to involve an inventive step (Article 33(3) PCT). Eventhough none of the documents relating to airway devices cite the specific method of manufacturing, the combined use of different plastics materials is known to the skilled person. It's application for an airway device is considered to be merely a case of applying the most recently available technology. Such an improvement does not meet the requirements of Article 33(3) PCT.

3 Dependent claims 2-24 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in

respect of inventive step (Article 33(3) PCT). The reasons therefore are the following:

Claims 2, 3 and 22 - 24:
These claims relate to the hardness of various components of the airway device. In view of the problem of preventing damage to the patients laryngeal tissues, it appears obvious to select the cuff material with the lowest hardness (see e.g. US-A-3734100). It will likewise be obvious to the skilled person that this same material will not necessarily be suitable for those parts of the airway device that need to be more rigid.
The use of the term "substantially" in claim 22 creates doubt as to when the hardness of the materials used in the same or different.

Claims 4 and 5:
These claims relate to the shape of the cross-section of the airway tube. The documents in the search report show identical shapes. Additionally, it is noted that the term "substantially" does not allow the reader to determine if a cross-section is circular or ellipsoid.

Claims 6 to 9:
These claims relate to a gastric tube. Document WO-A-00/09189 shows identical features.

Claims 10 - 12:
These claims relate to flexible flanges on the face of the cuff. Document EP-A-0389272 discloses identical features (see column 8, lines 4 to 8).

Claims 13 - 16:
These claims relate to a connector for connecting the airway device to a gas supply. These features are disclosed in document WO-A-00/09189 (see page 24, lines 25 to 29 and page 28, lines 20 to 23)

Claims 17 to 19:
These claims relate to the anatomical fit of the cuff. Contrary to the requirements of Rule 6.3(a) PCT, they have been formulated by the result to be achieved. The

features of these claims can therefore not be considered to be different from those disclosed in documents EP-A-0389272 or WO-A-00/09189.

Claims 20 and 21:
These claims relate to the place and shape of the cup. They are considered to be standard features of an airway device, which are also disclosed in document EP-A-0389272.

Re Item VI
Certain documents cited

The following document was published later, but filed earlier than the filing date of the application in suit. It does not constitute prior art for the purposes of Article 33(2) PCT, but is cited under Rule 70.10 PCT.

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO-A-2004/016308	26.02.2004	14.08.2003	14.08.2002